Package leaflet: Information for the patient

Donepezil Krka 5 mg film-coated tablets
Donepezil Krka 10 mg film-coated tablets
donepezil hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Donepezil Krka is and what it is used for

Donepezil Krka contains the active substance donepezil hydrochloride. Donepezil Krka (donepezil hydrochloride) belongs to a group of medicines called acetylcholinesterase inhibitors. Donepezil increases the levels of a substance (acetylcholine) in the brain involved in memory function by slowing down the breakdown of acetylcholine.

It is used to treat the symptoms of dementia in people diagnosed as having mild and moderately severe Alzheimer's disease. The symptoms include increasing memory loss, confusion and behavioural changes. As a result, sufferers of Alzheimer's disease find it more and more difficult to carry out their normal daily activities.

Donepezil Krka is for use in adult patients only.

2. What you need to know before you take Donepezil Krka

Do not take Donepezil Krka
- if you are allergic to donepezil hydrochloride, to piperidine derivatives or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Donepezil Krka if you have or have had:
- stomach or duodenal ulcers
- seizures (fits) or convulsions
- a heart condition (such as irregular or very slow heart beat, heart failure, myocardial infarction)
- a heart condition called 'prolonged QT interval' or a history of certain abnormal heart rhythms called Torsade de Pointes or if anyone in your family have 'prolonged QT interval')
- low levels of magnesium or potassium in your blood
- asthma or other long term lung disease
- liver problems or hepatitis
- difficulty passing urine or mild kidney disease

Also tell your doctor if you are pregnant or think you might be pregnant.

Children and adolescents
Donepezil Krka is not recommended for use in children and adolescents (younger than 18 years of age).

Other medicines and Donepezil Krka
Tell your doctor or pharmacist if you are taking, have recently taken or might take use any other medicines, including medicines obtained without a prescription.
It also applies to medicines you may take sometimes in the future if you continue to take Donepezil Krka. This is because these medicines may weaken or strengthen the effects of Donepezil Krka.

In particular it is important to tell your doctor if you are taking any of the following types of medicines:
- medicines for heart rhythm problems e.g. amiodarone, sotalol
- medicines for depression e.g. citalopram, escitalopram, amitriptyline, fluoxetine
- medicines for psychosis e.g. pimozide, sertindole, ziprasidone
- medicines for bacterial infections e.g. clarithromycin, erythromycin, levofloxacin, moxifloxacin, rifampicin
- anti-fungal medicines e.g. ketoconazole
- other Alzheimer's disease medicines, e.g. galantamine or rivastigmine,
- pain killers or treatment for arthritis e.g. aspirin, non-steroidal anti-inflammatory (NSAID) drugs such as ibuprofen or diclofenac sodium
- anticholinergics medicines, e.g. tolterodine
- anticonvulsants e.g. phenytoin, carbamazepine
- medication for a heart condition e.g. quinidine, beta-blockers (propranolol and atenolol)
- muscle relaxants e.g. diazepam, succinylcholine
- general anaesthetic
- medicines obtained without a prescription e.g. herbal remedies

If you are going to have an operation that requires you to have a general anaesthetic, you should tell your doctor and the anaesthetist that you are taking Donepezil Krka. This is because your medicine may affect the amount of anaesthetic needed.

Donepezil Krka can be used in patients with kidney disease or mild to moderate liver disease. Tell your doctor first if you have kidney or liver disease. Patients with severe liver disease should not take Donepezil Krka.

Tell your doctor or pharmacist the name of your caregiver. Your caregiver will help you to take your medicine as it is prescribed.

Donepezil Krka with food, drink and alcohol
Food will not influence the effect of Donepezil Krka.
Donepezil Krka should not be taken with alcohol because alcohol may change its effect.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Donepezil Krka should not be used while breastfeeding.

Driving and using machines
Alzheimer's disease may impair your ability to drive or operate machinery and you must not perform these activities unless your doctor tells you that it is safe to do so.

Also, your medicine can cause tiredness, dizziness and muscle cramp. If you experience any of these effects you must not drive or operate machinery.

Donepezil Krka contains lactose.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Donepezil Krka

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much Donepezil Krka should you take
Initially, the recommended dose is 5 mg (one white tablet) every night.
If you experience abnormal dreams, nightmares or difficulty in sleeping (see section 4) your doctor may advise you to take Donepezil Krka in the morning.
After one month, your doctor may tell you to take 10 mg (one yellow tablet) every night.

The tablet strength you will take may change depending on the length of time you have been taking the medicine and on what your doctor recommends. The maximum recommended dose is 10 mg each night.

Always follow your doctor's, or pharmacist's advice about how and when to take your medicine.
Do not alter the dose yourself without your doctor's advice.

How to take your medicine
Swallow your Donepezil Krka tablet with a drink of water before you go to bed at night.

Use in children and adolescents
Donepezil Krka is not recommended for use in children and adolescents (younger than 18 years of age).

If you take more Donepezil Krka than you should
Contact your doctor or the nearest hospital emergency department immediately if you take more of the medicine than you should. Take this leaflet and any remaining tablets with you.
Overdose symptoms may include nausea (feeling sick) and vomiting (being sick), drooling, sweating, slow heart rate, low blood pressure (light-headedness or dizziness when standing), breathing problems, losing consciousness and seizures (fits) or convulsions.

If you forget to take Donepezil Krka
If you forget to take your medicine, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you forget to take your medicine for more than one week, call your doctor before taking any more medicine.

If you stop taking Donepezil Krka
Do not stop taking the tablets unless told to do so by your doctor. If you stop taking Donepezil Krka, the benefits of your treatment will gradually fade away.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

For how long should you take Donepezil Krka?
Your doctor or pharmacist will advise you on how long you should continue to take your tablets. You will need to see your doctor from time to time to review your treatment and assess your symptoms.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported by people taking Donepezil Krka. **Tell your doctor if you have any of these effects while you are taking Donepezil Krk**a.

Serious side effects:
You must tell your doctor immediately if you notice these serious side effects mentioned. You may need urgent medical treatment.
- liver damage e.g. hepatitis. The symptoms of hepatitis are feeling or being sick, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes and dark coloured urine (may affect up to 1 in 1,000 people).
- stomach or duodenal ulcers. The symptoms of ulcers are stomach pain and discomfort (indigestion) felt between the navel and the breast bone (may affect up to 1 in 100 people).
- bleeding in the stomach or intestines. This may cause you to pass black tar like stools or visible blood from the rectum (may affect up to 1 in 100 people).
- seizures (fits) or convulsions (may affect up to 1 in 100 people).
- fever with muscle stiffness, sweating or a lowered level of consciousness (a disorder called "Neuroleptic Malignant Syndrome") (may affect up to1 in 10,000 people).
- muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell, have a high temperature or have dark urine. They may be caused by an abnormal muscle breakdown which can be life threatening and lead to kidney problems (a condition called rhabdomyolysis) (may affect up to 1 in 10,000 people).

Frequency not known:
- Changes in the heart activity which can be seen on an electro-cardiogram (ECG) called 'prolonged QT interval'
- Fast, irregular heart beat, fainting which could be symptoms of a life-threatening condition known as Torsade de Pointes

Other side effects
<u>Very common side effects</u> (may affect more than 1 in 10 people):
- diarrhoea
- feeling sick (nausea)
- headache

<u>Common side effects</u> (may affect up to 1 in 10 people):
- muscle cramp
- tiredness
- difficulty in sleeping (insomnia)
- the common cold
- loss of appetite
- hallucinations (seeing or hearing things that are not really there)
- unusual dreams including nightmares
- agitation
- aggressive behaviour
- fainting
- dizziness
- stomach feeling uncomfortable
- rash
- itching
- passing urine uncontrollably
- pain
- accidents (patients may be more prone to falls and accidental injury)

<u>Uncommon side effects</u> (may affect up to 1 in 100 people):

- slow heart beat
- salivary hypersecretion

Rare side effects (may affect up to 1 in 1,000 people):
- stiffness, shaking or uncontrollable movement especially of the face and tongue but also of the limbs

Not known (frequency cannot be estimated from the available data):
- libido increased, hypersexuality
- Pisa syndrome (a condition involving involuntary muscle contraction with abnormal bending of the body and head to one side)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Donepezil Krka

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the packaging after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Donepezil Krka contains
- The active substance is donepezil hydrochloride.
  Each film-coated tablet contains 5 mg donepezil hydrochloride (as monohydrate) equivalent to 4.56 mg donepezil.
  Each film-coated tablet contains 10 mg donepezil hydrochloride (as monohydrate) equivalent to 9.12 mg donepezil.
- The other ingredients are lactose monohydrate, cellulose microcrystalline, maize starch, hydroxypropylcellulose and magnesium stearate in the tablet core and titanium dioxide (E171), hypromellose 5cp, macrogol 400, iron oxide, yellow (E172) – only in 10 mg tablets in the film coating.
  See section 2 “Donepezil Krka contains lactose”.

What Donepezil Krka looks like and contents of the pack

5 mg tablets are white to nearly white, rounded, diameter approx. 7 mm, biconvex, film-coated tablets.
10 mg tablets are yellowish-brown, rounded, diameter approx. 9 mm, biconvex, film-coated tablets.

Donepezil Krka is available in boxes containing:
- 7, 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98 and 100 film-coated tablets in blisters,
- 250 film-coated tablets in a plastic tablet container with a tamper-evident screw closure.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Name of the Member State	Name of the medicine
Austria, Belgium, Cyprus, Denmark, Finland, France, Ireland, Norway, Sweden	Donepezil Krka
Greece	Donepezil/Krka
Bulgaria, Czech Republic, Germany, Hungary, Italy, Romania, Spain, Slovak Republic	Yasnal
Portugal	Donepezilo Krka
United Kingdom (Northern Ireland)	Donepezil hydrochloride

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